

DOCKET NO.: C215

PATENT

Application No.: 09/975,350

Office Action Dated: April 2, 2008

This listing of claims will replace all prior versions and listings of claims in the application.

### Listing of the Claims

1. (currently amended) A non-aqueous liquid solution comprising a modafinil compound, at least one organic solvent, and at least one surfactant, characterized in that the solution spontaneously forms an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium.
2. canceled.
3. (previously presented) The solution of claim 1, wherein the modafinil compound is modafinil.
4. (previously presented) The solution of claim 1, wherein the solution is pharmaceutically acceptable.
5. canceled.
6. canceled.
7. canceled.
8. (previously presented) The solution of claim 1, wherein the surfactant or surfactants comprise from about 0.5% to about 50% (w/w) of the solution.
9. (previously presented) The solution of claim 8, wherein the surfactant or surfactants comprise from about 1% to about 20% (w/w) of the solution.
10. (previously presented) The solution of claim 1, wherein the surfactant or surfactants is a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of polyethylene glycol, a medium chain

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monoglyceride, a medium chain fatty acid ester, d- $\alpha$ -tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, or an ethoxylated hydroxystearic acid.

11. (previously presented) The solution of claim 10, comprising a first surfactant and a second surfactant.

12. (previously presented) The solution of claim 11, wherein the second surfactant is a polyoxyethylene sorbitan fatty acid ester.

13. (previously presented) The solution of claim 12, wherein the second surfactant is sorbitan monolaurate or Polysorbate 80.

14. canceled

15. (currently amended) The solution of ~~claim 14~~claim 1, wherein the organic solvent is at least one solvent selected from the group consisting of glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, tetraglycol, a medium chain length monoglyceride, and a polyethylene glycol.

16. (previously presented) The solution of claim 15, further comprising benzyl alcohol,  $\alpha$ -phenethyl alcohol or  $\beta$ -phenethyl alcohol.

17. (previously presented) The solution of claim 3, wherein modafinil is present in the solution at a concentration of about 1 to about 500 mg/ml.

18. (previously presented) The solution of claim 17, wherein modafinil is present in the solution at a concentration of about 1 to about 200 mg/ml.

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19. (previously presented) The solution of claim 1, wherein the solution comprises a modafinil compound at a concentration of about 1 to about 100 mg/ml; a first surfactant selected from a polyoxyethylene sorbitan fatty acid ester, a polyethylene glycol ether, a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, a medium chain monoglyceride, a medium chain fatty acid ester, d- $\alpha$ -tocopheryl polyethylene glycol succinate, a polyethylene/propylene glycol copolymer, block copolymers of ethylene oxide and propylene oxide, a polyoxyl stearate, an ethoxylated castor oil, and an ethoxylated hydroxystearic acid; a second surfactant selected from a polyoxyethylene sorbitan fatty acid ester; and an organic solvent selected from glycerin, propylene glycol, diethylene glycol ethyl ether, propylene carbonate, tetraglycol, a medium chain length monoglyceride, and a polyethylene glycol.

20. (previously presented) The solution of claim 19, wherein the modafinil compound is modafinil.

21. (previously presented) The solution of claim 20, wherein the first surfactant is a saturated polyglycolized glyceride, a fatty acid ester of a polyethylene glycol, or a medium chain monoglyceride; the second surfactant is a polyoxyethylene sorbitan fatty acid ester; and the organic solvent is a polyethylene glycol.

22. (previously presented) The solution of claim 21, wherein the first surfactant is glyceryl caprylate/caprate, glyceryl monocaprylate or polyethoxylated (40) stearic acid; the second surfactant is sorbitan monolaurate; and the organic solvent is PEG-300 or PEG-400.

23. (previously presented) The solution of claim 22, wherein the solution comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl caprylate/caprate (w/w/w).

24. (previously presented) The solution of claim 22, wherein the solution comprises 90% PEG-400, 5% sorbitan monolaurate, 5% glyceryl monocaprylate (w/w/w).

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25. (previously presented) The solution of claim 22, wherein the solution comprises 90% PEG-400, 5% sorbitan monolaurate, 5% polyethoxylated (40) stearic acid (w/w/w).

26. (previously presented) The solution of claim 21, wherein the first surfactant is glyceryl caprylate/caprate, glyceryl monocaprylate, polyethoxylated (40) stearic acid or a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate; the second surfactant is polyoxyethylene (80) sorbitan monooleate; and the organic solvent is PEG-300 or PEG-400.

27. (previously presented) The solution of claim 26, wherein the solution comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl caprylate/caprate (w/w/w).

28. (previously presented) The solution of claim 26, wherein the solution comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% glyceryl monocaprylate (w/w/w).

29. (previously presented) The solution of claim 26, wherein the solution comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% polyethoxylated (40) stearic acid (w/w/w).

30. (previously presented) The solution of claim 26, wherein the solution comprises 70% PEG-400, 15% polyoxyethylene (80) sorbitan monooleate, 15% of a mixture of polyoxyethylene glyceryl caprylate and polyoxyethylene glyceryl caproate (w/w/w).

31. (previously presented) The solution of claim 10, wherein the solution comprises Polysorbate 80, glyceryl caprylate/caprate and a mixture of glyceryl tricaprate and glyceryl tricaprilate.

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32. (previously presented) The solution of claim 1, comprising one or more unit doses of a modafinil compound.

33. (previously presented) The solution of claim 32, comprising one unit dose of a modafinil compound.

34. (previously presented) The solution of claim 33, wherein the unit dose comprises 200 mg of a modafinil compound.

35. (previously presented) The solution of claim 33, wherein the unit dose comprises 100 mg of a modafinil compound.

36. (withdrawn) A method of preparing an aqueous, liquid, homogeneous, stable composition of non-crystalline particles, comprising the steps of:

- (a) preparing a non-aqueous solution comprising a modafinil compound and at least one surfactant; and
- (b) contacting the solution with an aqueous medium to spontaneously form an aqueous, liquid, homogeneous, stable composition of non-crystalline particles.

37. (withdrawn) The method of claim 36, wherein the solution is contacted with an aqueous medium in vitro.

38. (withdrawn) The method of claim 36, wherein the solution is contacted with an aqueous medium in vivo.

39. (withdrawn) The method of claim 36, wherein the modafinil compound is modafinil.

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40. (withdrawn) The method of claim 36, wherein the surfactant or surfactants are present in an amount from about 1% to about 50%.

41. (withdrawn – currently amended) A method of treating a disease or disorder in a subject, comprising administering to a subject a therapeutically effective amount of a non-aqueous liquid solution comprising a modafinil compound, at least one organic solvent, and at least one surfactant, wherein the solution is characterized by the fact that it spontaneously forms an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium, and wherein the non-aqueous solution is administered for the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive dysfunction or fatigue; or for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain.

42. (withdrawn – currently amended) A method of treating a disease or disorder in a subject, comprising:

(a) preparing a non-aqueous liquid solution comprising a modafinil compound, at least one organic solvent, and at least one surfactant;

(b) contacting the non-aqueous solution with an aqueous medium to spontaneously form an aqueous, liquid, homogeneous, stable composition of non-crystalline particles; and

(c) administering a therapeutically effective amount of the aqueous, liquid, homogeneous, stable composition of non-crystalline particles to a subject;

wherein the aqueous, liquid, homogeneous, stable composition of non-crystalline particles is administered for the treatment of sleepiness, tiredness, Parkinson's disease, cerebral ischemia, stroke, sleep apneas, eating disorders, attention deficit hyperactivity disorder, cognitive dysfunction or fatigue; or for the promotion of wakefulness, stimulation of appetite, or stimulation of weight gain.

43. (withdrawn) The method of claim 40, wherein the modafinil compound is modafinil.

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44. canceled.

45. (previously presented) The solution of claim 3, wherein upon administration of the solution to a subject in need thereof, modafinil has a blood serum level of about 0.05 to about 30 µg/ml in said subject.

46. (previously presented) The solution of claim 45, wherein the blood serum level is from about 1 to about 20 µg/ml.

47. (previously presented) The solution of claim 1, wherein the solution is suitable for oral administration to a subject.

48. (previously presented) The solution of claim 47, wherein the solution is encapsulated within a capsule.

49. (previously presented) The solution of claim 48, wherein the capsule is a soft gelatin capsule.

50. (previously presented) The solution of claim 48, wherein the capsule is a hard capsule.

51. canceled.

52. canceled.

53. canceled.

54. canceled.

55. (previously presented) The solution of claim 1, wherein the modafinil compound is the levorotatory form of modafinil.

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56. (withdrawn) The method of claim 36, wherein the modafinil compound is the levorotatory form of modafinil.

57. (withdrawn) The method of claim 40, wherein the modafinil compound is the levorotatory form of modafinil.

58. (withdrawn) The method of claim 41, wherein the modafinil compound is modafinil.

59. (previously presented) The solution of claim 14, wherein the organic solvent has an average molecular weight of about 1500 daltons or less.

60. (withdrawn) The method of claim 42, wherein the modafinil compound is modafinil.

61. canceled.

62. canceled.

63. (previously presented) The solution of claim 19, wherein the modafinil compound is the levorotatory form of modafinil.

64. (withdrawn) The method of claim 41, wherein the modafinil compound is the levorotatory form of modafinil.

65. (withdrawn) The method of claim 42, wherein the modafinil compound is the levorotatory form of modafinil.

66. (previously presented) The solution of claim 18, wherein modafinil is present in the solution at a concentration of about 20 to about 80 mg/ml.



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67. canceled.

68. canceled.